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A wearable in-ear encephalography sensor for monitoring sleep: preliminary observations from nap studies

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- Conception and design: DL, VG, MJM, DPM
- Analysis and interpretation: DL, VG, MJM, DPM
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Abstract

Rationale: To date the only quantifiable measure of neural changes that define sleep is electroencephalography (EEG). Although widely used for clinical testing, scalp-electrode EEG is costly and poorly tolerated by sleeping patients.

Objective: This is a pilot study to assess the agreement between EEG recordings obtained from a new ear-EEG sensor and those obtained simultaneously from standard scalp electrodes.

Methods: Participants were 4 healthy men, ages 25 to 36 years. During naps, EEG tracings were recorded simultaneously from the ear sensor and standard scalp electrodes. A clinical expert, blinded to the data collection, analyzed 30-second epochs of recordings from both devices using standardized criteria. The agreement between scalp- and ear-recordings was assessed.

Measurements and Main Results: We scored 360 epochs (scalp-EEG and ear-EEG) of which 254 (70.6%) were scored as non-rapid-eye movement (NREM) sleep using scalp-EEG. The ear-EEG sensor had a sensitivity of 0.88 (95% CI 0.82 to 0.92) and specificity of 0.78 (95% CI 0.70 to 0.84) in detecting N2/N3 sleep. The kappa coefficient, between the scalp- and ear-EEG, was 0.65 (95% CI 0.58 to 0.73). As a sleep monitor (all NREM sleep stages versus wake), the in-ear sensor had a sensitivity of 0.91 (95% CI 0.87 to 0.94) and specificity of 0.66 (95% CI 0.56 to 0.75). The kappa coefficient was 0.60 (95% CI 0.50 to 0.69).

Conclusions: Substantial agreement was observed between recordings derived from a new ear-EEG sensor and conventional scalp electrodes on 4 healthy volunteers during daytime naps.

Sleep is critical for health (1), with sleep disorders linked to an increased risk of systemic hypertension, cardiovascular disease, stroke (2,3), cognitive dysfunction (4) and dementia (5). Nocturnal electroencephalography (EEG), requiring the placement of up to 10 electrodes on the scalp in standardized positions (6), is the gold standard for measurement of the neural changes that define sleep and is routinely used in the diagnosis of disorders. However, the approach is time consuming and can potentially disrupt sleep through the discomfort caused to the patient. It can also require an overnight stay in hospital, which is inconvenient and costly. A growing demand for ambulatory alternatives has led to development of home sleep monitoring and a greater diagnostic role for primary care physicians (7). Indeed, it is now estimated that the combined US and European market for clinical and ambulatory sleep devices is worth \$96.5 million.

Portable sleep monitors that enable longer term monitoring could facilitate the broader aim of establishing links between sleep disorders and daytime function. For example, sleep tests performed in the clinical environment cannot quantify the safety and occupational risks of sleepiness (caused by lack of sleep) accurately (8). There is, therefore, considerable need for comfortable, wearable monitors that can directly monitor long-term EEG in natural environments (9, 10, 11).

Existing EEG systems for the diagnosis of sleep-disordered breathing utilize scalp electrodes to define changes in conscious state. This study tests, for the first time, EEG recorded from within the ear canal during sleep. This is achieved by embedding electrodes on a viscoelastic earpiece to preserve the relevant signal components (11). The concept satisfies key wearable needs (comfortable, stable, non-stigmatizing), thereby providing a convenient solution for long-term EEG recording in natural environments. The aim of this pilot study is to determine the agreement between the ear-EEG sensor and gold standard scalp EEG electrodes for detecting sleep-related EEG changes.

Methods

Setting

This study was undertaken at Imperial College London, UK, between May 2014 and March 2015.

Participants: We recruited 4 healthy participants with no history of snoring, sleep disorders or neurological disease. The participants were male, non-smokers, ages 25, 28, 32, and 36 years, with respective body mass indices of 25.7, 20.5, 28 and 24 Kg^m². Written, informed consent was obtained from all participants (Joint Research Office at Imperial College London, reference ICREC 12_1_1).

Ear-EEG technology

The recently-developed ear-EEG sensor (11) comprised a memory-foam viscoelastic earpiece (diameter approximately 12 mm, length approximately 25 mm) with two electrodes at diametrically-opposed locations, made from flexible conductive cloth (surface area approximately 75 mm²), as shown in Figure 1. The viscoelastic nature of the earpiece, coupled with the flexibility of the electrodes, provided a key advantage compared with existing ear-EEG sensors, both personalized and generic (11).

Following insertion into the ear canal, the sensor expanded and redistributed pressure evenly along the entirety of its contact surface, thus providing a stable interface with the skin. The stability of the viscoelastic sensors was such that mechanical disturbances in the low-frequency range were greatly attenuated, facilitating uncompromised patterns of N2/N3 sleep, as illustrated in Figure 2.

Protocol

Sleep studies were performed in the late afternoon. Participants were instructed to reduce their sleep to 4–5 hours on the night prior to the study, and to refrain from napping or caffeine on the day of the study.

The setup time for each participant was between 60 and 90 minutes (ear-EEG sensors and scalp EEG). Earwax was removed from the ear canals with cotton buds. Skin on the relevant outer parts of the ear (earlobe, helix) and scalp was abraded (Nuprep gel). EEG was simultaneously recorded from the in-ear and standard on-scalp electrodes using the g-USBamp, a 24-bit biosignal amplifier (g.tec medical engineering, <http://www.gtec.at/>) which enables up to four independent recording configurations.

Scalp-EEG was obtained from electrodes positioned according to the international 10-20 system: mastoid (A1,A2) and central (C3,C4) regions. The ground electrode was placed on the forehead. Standard reference configurations for sleep measurements were utilized (C3-A2 and C4-A1).

Ear-EEG was obtained from the left (and right) ear from two electrodes placed at diametrically opposed locations along the ear canal wall, referenced to a gold-cup electrode placed behind the left (and right) helix. The ground electrode was placed on the left (and right) earlobe. All data was acquired with a sampling rate of 1.2 kS/s.

Once the electrodes were attached, the participants reclined in a chair in a dark and quiet room and were allowed to sleep. Recordings continued for at least 45 minutes, with bursts of 10 s noise played through a loudspeaker at random intervals to increase the number of wake / sleep transitions.

Analysis

Pre-processing operations were applied to the EEG prior to scoring. In the case of scalp-EEG, all data was bandpass filtered using a 4th order Butterworth filter with cutoff frequencies at 1 and 20 Hz. To optimize the blinded nature of the scoring process, the ear-EEG amplitudes were scaled to match the range of scalp-EEG. The low-pass cutoff was the same as for scalp-EEG (20 Hz), but the high-pass cutoff was adjusted depending on the level of low-frequency interference present in the ear-EEG recording; for participants 1 and 3 the cutoff was 1 Hz, and for participants 2 and 4 it was 2 Hz, as

greater low-frequency interference was observed during data collection in participants 2 and 4.

The EEG recordings (four scalp, four in-ear) were randomized and blinded. The epochs were scored using the American Academy of Sleep Medicine (AASM) sleep-scoring criteria. Scoring was performed for the standard epoch size of 30 s, giving 90 epochs per recording. The clinical expert had six years of EEG scoring experience and was blinded to the data recording method.

Statistical analysis

Analysis was carried out to determine the level of agreement between the scores obtained with the ear- and scalp-EEG for two scenarios: (1) distinguishing between unambiguous N2/N3 sleep and wake plus light sleep (W/N1); (2) distinguishing between NREM sleep – comprising stages N1, N2 and N3 – and W.

The performance of ear-EEG for sleep detection was evaluated by calculating the sensitivity $TP/(TP+FN)$, specificity $TN/(TN+FP)$ and accuracy $(TP+TN)/(TP+FP+TN+FN)$. The kappa coefficient (12) was calculated for Scenarios 1 & 2. A score of <0 indicates less than chance agreement, 0.01–0.20 slight agreement, 0.21–0.40 fair agreement, 0.41–0.60 moderate agreement, 0.61–0.80 substantial agreement, and 0.81–0.99 almost perfect agreement (13). The confidence interval (CI) of the coefficient was also calculated from its standard error.

Results

All participants were able to sleep and, as expected, no REM sleep was recorded. The number and percentage of W, N1, N2 and N3 epochs, scored using ear- and scalp-EEG, are shown in Table 1. The sensitivity, specificity and accuracy of ear-EEG in detecting N2/N3 and all NREM sleep stages are given in Table 2.

In Scenario 1, the sensitivity for the detection of N2/N3 using ear-EEG was 0.88 (95% CI 0.82 to 0.92) and the specificity was 0.78 (95% CI 0.70 to 0.84). The level of agreement with scalp-EEG was substantial, as illustrated by the contingency table (Table 3) and a kappa coefficient of 0.65 (95% CI 0.58 to 0.73). The higher sensitivity indicated a bias towards scoring wake epochs as sleep; this was likely caused by the presence of greater low-frequency activity in ear-EEG during all epochs.

For Scenario 2, the sensitivity, specificity and accuracy of ear-EEG in detecting NREM sleep (all stages) are shown in Table 2. The corresponding contingency values are given in Table 3. The bias increased for the task of NREM sleep detection (all stages), and the specificity of ear-EEG decreased to 0.66 (95% CI 0.56 to 0.75). This can be explained by the large number of N1 epochs (14.1%); the distinction between wake and N1 can be subtle and difficult to perform accurately. The results for Participant 4 were the weakest among all four participants. This was caused by the presence of low-frequency interference, such that wake epochs were incorrectly scored as sleep. The large CI of the group mean results was likely caused by the small number of participants for this proof-of-concept study. Overall, the ability of the ear-EEG to distinguish between wake and NREM sleep can be summarized by the kappa coefficient of 0.60 (95% CI 0.50 to 0.69), a finding that indicates a moderate to substantial level of agreement with scalp-EEG.

Discussion

The new ear-EEG sensor recorded sleep at a moderate to substantial level of agreement with the gold standard (scalp) EEG. The errors were caused in part by the similarity in the EEG patterns recorded by the ear EEG sensor between wakefulness (W) and light (N1) sleep. Therefore, the agreement was closer between the ear and scalp-EEG when distinguishing unambiguous N2/N3 sleep from wakefulness combined with light sleep (W/N1). In both cases, the specificity was lower than the sensitivity, which can be explained by the presence of low-frequency activity in ear-EEG resulting in

some wake and N1 epochs being incorrectly labeled as N2/N3.

The ability to monitor EEG from a comfortable ear sensor could provide opportunities to improve the diagnosis of sleep disorders such as obstructive sleep apnea. Compared with other portable EEG systems, which rely on scalp electrodes with a cap and/or adhesives, the comfortable and stable nature of the in-ear sensor is more suitable for overnight recordings as it does not interfere with the patient's sleep.

The viscoelastic in-ear sensor used in this study also offers several advantages compared to the original prototype that we have previously reported (9, 10) and more recent ear-EEG developments (14, 15) which use silicone earpieces. Firstly, the viscoelastic sensor is more cost-effective as it fits any adult ear – the original prototype was customized to the ear like a hearing aid, requiring a costly and time-consuming manufacturing process. Secondly, unlike silicone earbuds which provide suboptimal conformance to the shape of the ear canal, viscoelastic earbuds expand and redistribute pressure evenly along the contact surface. In this way, the sensor provides a more stable interface with the skin, which reduces mechanical artefacts caused by motion or cardiac pulsation (11). This feature is critical for sleep monitoring where robust and stable recordings are paramount, particularly at low EEG frequencies. Future developments will utilize the interface to add additional physiological sensors such as heart rate and temperature.

Limitations

A limitation of the present study was the overly simple fashion in which the ear-EEG was adjusted to match scalp-EEG (scaling, different filtering parameters for Participants 2 and 4). To date, ear-EEG has been validated primarily on averaged responses that do not account for more qualitative differences with standard EEG, as well as occasional transient and spurious activity. Ear-EEG can exhibit greater low-frequency activity, making it visually dissimilar to activity recorded at more conventional scalp electrode locations. This is exemplified by Figure 2 (Panel A), which illustrates that ear-EEG can

contain low-frequency signal dynamics even during wakefulness. This is likely the cause for the sensitivity bias reported in this manuscript, as low-frequency EEG is associated with sleep.

Another limitation is the small number of participants ($n=4$). However, our intention was to provide an initial proof-of-concept study to illustrate the feasibility of in-ear sensing in sleep detection, shown by testing multiple epochs in several sleep stages; specifically linking N2 and N3 sleep in order to compare lower EEG frequencies.

Implications

The ear-EEG sensor offers a discreet way to continuously monitor sleep and, if verified on a broad spectrum of subjects, the potential clinical implications are many and varied. Monitoring excessive daytime sleepiness is presently difficult and performed using subjective tests such as Epworth Sleepiness Scale questionnaire (16), or objective tests such as the Maintenance of Wakefulness Test or the Multiple Sleep Latency Test. However, subjective tests are not always accurate (17), while access to objective tests is limited. The ear-EEG sensor may enable direct monitoring of sleep-related changes in EEG throughout both the day and night in real-world environments, and ultimately offer a viable solution to the challenges of accurately but easily measuring sleep and sleepiness.

Table 1. Number and percentage of Wake, N1, N2 and N3 sleep epochs. Total number of epochs = 360; n=4.

	Wake	N1 sleep	N2 sleep	N3 sleep
Scalp-EEG	106 (29.4%)	54 (15.0%)	153 (42.5%)	47 (13.1%)
Ear-EEG	92 (25.6%)	57 (15.8%)	181 (50.3%)	30 (8.3%)

Table 2. Performance of ear-EEG in correctly detecting N2/N3 sleep (stages N2 and N3) from wake and light sleep (W/N1) in Scenario 1, and sleep (stages N1, N2 and N3) from wake in Scenario 2, using scalp electrodes as the gold standard.

Scenario 1	N2/N3 [scalp]	N2/N3 [ear]	TP	Sen	Spc	Acc
1	17 (18.9%)	9 (10.0%)	9	0.53	1.00	0.91
2	66 (73.3%)	59 (65.6%)	55	0.83	0.83	0.83
3	81 (90.0%)	78 (86.7%)	78	0.96	1.00	0.97
4	36 (40.0%)	65 (72.7%)	33	0.92	0.41	0.61
all	200 (55.6%)	211 (58.6%)	175	0.88	0.78	0.83
Scenario 2	Sleep [scalp]	Sleep [ear]	TP	Sen	Spc	Acc
1	30 (33.3%)	14 (15.6%)	14	0.47	1.00	0.82
2	76 (84.4%)	75 (83.3%)	70	0.92	0.64	0.88
3	82 (91.1%)	89 (98.9%)	82	1.00	0.13	0.92
4	66 (73.3%)	90 (100%)	66	1.00	0.00	0.73
all	254 (70.6%)	268 (74.4%)	232	0.91	0.66	0.84

N2/N3 [scalp] denotes the number of N2 & N3 epochs defined by scalp-EEG scores in Scenario 1, N2/N3 [ear] number of N2 & N3 epochs defined by ear-EEG scores in Scenario 1, Sleep [scalp] denotes the number of sleep epochs defined by scalp-EEG scores in Scenario 2, Sleep [ear] number of sleep epochs defined by ear-EEG scores in Scenario 2, TP: true positives, Sen: sensitivity, Spc: specificity, Acc: accuracy.

Table 3. Contingency table for all participants. Scenario 1: wake and light sleep (Wake/N1) versus N2/N3 sleep (stages N2 and N3), and Scenario 2: wake versus sleep (N1, N2 and N3)

Scenario 1		Wake/N1 [scalp]	N2/N3 [scalp]
	Wake/N1 [ear]	124 (34.4%)	25 (6.9%)
	N2/N3 [ear]	36 (10.0%)	175 (48.6%)
Scenario 2		Wake [scalp]	Sleep [scalp]
	Wake [ear]	70 (19.4%)	22 (6.1%)
	Sleep [ear]	36 (10.0%)	232 (64.4%)

The kappa coefficient: Scenario 1; 0.65 (95% CI 0.58 to 0.73) Scenario 2; 0.60 (95% CI 0.50 to 0.69)

Figure 1

The in-ear sleep sensor is shown in panels A & B. A: sketch of the right earpiece and its location inside the ear. B: A photograph of the prototype earpiece worn in-ear. C: The prototype electronics platform, comprising low-power microcontroller, analog front end for physiological signals, SD memory card and 110 mAh battery.

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Figure 2

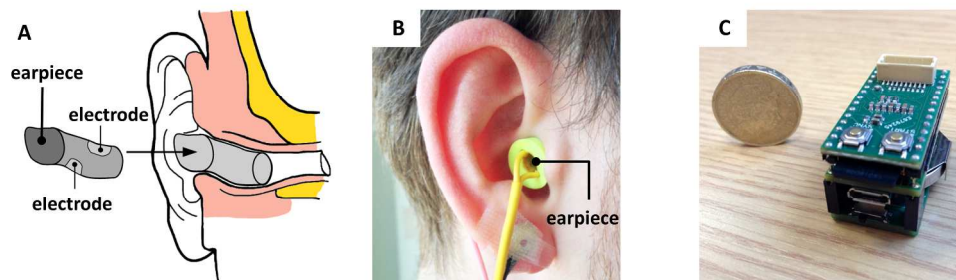
Time-domain EEG recorded from scalp and ear electrodes: 15s of ear- and scalp-EEG obtained during wake (Panel A) and stage N3 sleep (Panel B). Observe the presence of alpha activity (8-13 Hz) in ear-EEG in Panel A, and the absence of alpha activity in Panel B as well as increased theta (4-7 Hz) and delta (1-3 Hz) activity. For reference, the simultaneously-obtained trace using a conventional scalp electrode is also shown.

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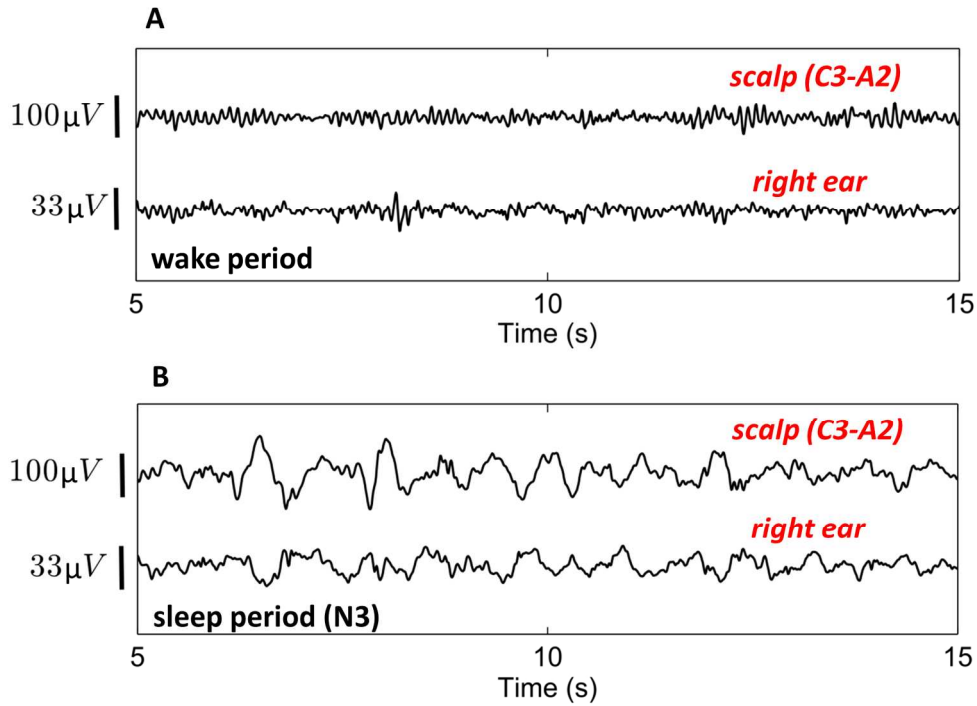
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